UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/910,354	07/20/2001	Kevin A. Jarrell	2003320-0032	2372

24280 7590 03/05/2010
CHOATE, HALL & STEWART LLP
TWO INTERNATIONAL PLACE
BOSTON, MA 02110

EXAMINER	
VOGEL, NANCY TREPTOW	

ART UNIT	PAPER NUMBER
1636	

NOTIFICATION DATE	DELIVERY MODE
03/05/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@choate.com

Office Action Summary	Application No. 09/910,354	Applicant(s) JARRELL ET AL.	
	Examiner NANCY VOGEL	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 06 January 2010.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1,2,4,5,14-17 and 19-21 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1, 2, 4, 5, 14-17, 19-21 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/6/10 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 4, 5, 12, 14-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Harney et al. (US Patent 6,495,318).

This rejection is maintained essentially for the reasons set forth in the previous Office action, mailed 7/6/09. To recapitulate:

Harney disclose a method of preparing a DNA vector, comprising providing at least two collections of nucleic acid molecules that are DNA vector fragments, wherein

each of the collections comprises alternative vector fragments to be included in the vector, wherein vector fragments within the first collection each comprise at least a first portion of a first vector element and a first portion of a second vector element (a first portion of an antibiotic resistance marker encoding gene, for instance) which first portion of the second vector element cannot alone provide a second vector element function (the function of antibiotic resistance); and vector fragments within the second collection each comprise a second portion of the second vector element (a second part of an antibiotic resistance encoding gene for instance), which second portion of the second vector element also cannot alone provide the second vector element function, the first and second portions of the second vector element being selected and the vector fragments being designed such that when a vector fragment from the first collection is ligated with a vector fragment from the second collection the second vector element function is reconstituted, and mixing at least one vector fragment from each collection with one another under linkage conditions so that a hybrid molecule in which each of the fragments is linked together is produced. See Figure Fig. 1 and col. 1, lines 58-col. 2, line 15, and see col. 17, lines 15-23). The reference discloses that the selected nucleic acid molecules contain at least one overhang that is complementary with an overhang on at least one of the other selected molecules (col. 2, lines 33-41). The reference discloses the further introduction of the hybrid molecule (ie vector) into a cell (see col. 56, lines 18-23). The reference discloses that each nucleic molecule in each of said collections contains at least a portion of a vector element such as a promoter, selectable marker, replication origin, transcription terminator, etc. (Fig. 1 and column 7,

lines 11-26). The reference discloses admixing under ligase conditions (see col. 17, lines 61-65). The vector fragments contain selectable or detectable genetic units (see Fig. 1). The reference discloses said method wherein the step of admixing further comprises admixing an isolated nucleic acid molecule containing insert sequence (ie the gene of interest in Fig. 1). The first vector element provides a first vector element function, such as a promoter (Fig. 1). The reference discloses that a marker gene may be split between two of the components, which is reconstituted upon ligation of the two components (col. 17 lines 15-23). The first vector element may also be considered to be the half restriction enzyme site present at the left of the fragments shown in Fig. 1, and thus they alone cannot provide a first vector element function i.e. a complete restriction site. The first portion of the first vector element may alternatively be considered the promoter present on the first element shown in Fig. 1. It is noted that the specification defines a vector “element” as “a region of nucleic acid sequence that imparts a particular functional or structural characteristic upon the molecule” (page 8 of the specification). Furthermore, each of the fragments in Fig. 1 may be considered to comprise a first or second portion of a second vector element, which if nucleic acid is inserted between said first and second portion, would prevent creation of the "second vector detection element"; a vector detection element may be a particular pattern of nucleic acid fragments produced upon restriction, and an insertion of nucleic acids between two portions of the "second vector detection element" would not create said "second vector detection element". Furthermore, a selectable marker gene which is split between two components or fragments, would fail to function if interrupted by a

DNA fragment inserted between the two components or fragments. Therefore, the claims are anticipated.

Applicants arguments have been considered but have not been found convincing. Applicants have argued that the reference does not disclose a "method in which an insert sequence prevents formation of a second vector detection element" and that Figure 1 does not disclose "a method in which restriction digestion an analysis of fragments is used to determine whether or nor not an insert detection element is present" (pages 6-7). However, the claims are not drawn to a method of detection of whether or not an insert detection element is present, but rather, are drawn to a method of preparing a DNA vector, comprising steps of providing certain collections of nucleic acid molecules and admixing said nucleic acid molecules to form a hybrid molecule. While the claims recite that certain elements are "detection elements", it is maintained that the elements disclosed in the reference can be considered "detection elements", since they could be detected by restriction fragment analysis. The reference does disclose a method of preparing a DNA vector, and Fig. 1 shows the elements that are utilized. Further, regarding applicant's arguments that "In this configuration [Harney's], the vector would ligate only if an insert was present. A second vector detection element would never form in the absence of an insert sequence because the ends between the portions of the element would not be compatible according to Harney's design". However, there appears to be no limitation in the instant claims reciting that the ends of particular elements are not compatible. Therefore, the applicant's arguments are not found convincing.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NANCY VOGEL whose telephone number is (571)272-0780. The examiner can normally be reached on 7:00 - 3:30, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/NANCY VOGEL/
Primary Examiner, Art Unit 1636

NV
3/1/10